K033395 page 1 of 2

510(k) Summary
CODMAN Dural Graft Implant

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Date: October 22, 2003

Contact Person

Elizabeth Dolan
Senior Regulatory Affairs Specialist
Telephone Number: (508) 828-3262
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Name of Device

Proprietary Name:	CODMAN Dural Graft Implant
Common Name:	Dura Substitute
Classification Name:	Dura Substitute

Device Classification

Dura Substitutes are Class II devices per 21 CFR § 882.5910.

Physical Description

The CODMAN Dural Graft Implant is a collagen sponge manufactured from processed bovine tendons. It is a sterile, absorbable implant intended for the repair of the patient's dura matter. The CODMAN Dural Graft Implant is designed to be a sutureless, onlay graft, but tensionless sutures can be used if preferred by the surgeon.

Indications for Use

The CODMAN Dural Graft Implant is intended for use in procedures where the repair or substitute of the patient dura mater is needed.

Device Testing

The CODMAN Dural Graft Implant was subjected to biocompatibility testing, physical and mechanical testing, and an animal study. Testing was

conducted with consideration to FDA's "Guidance Document for Dura Substitute Devices: Guidance for Industry" (Nov. 9, 2000).

The physical and mechanical properties of the sterilized CODMAN Dural Graft Implant were tested and compared to a predicate device. Both devices performed similarly. These tests included: device thickness, tensile strength, suture retention strength, burst strength, and surface structure (Scanning Electron Microscopy).

The CODMAN Dural Graft Implant and its predicate device performed similarly in an *in vivo* animal study. Animals implanted with either device showed no signs of CSF leakage, infection, hydrocephalus, hemorrhage or toxicity. Histopathologic samples from animals implanted with either CODMAN Dural Graft Implant or its predicate device were similar in terms of adhesion formation, device resorption, foreign body reactions, other tissue reactions, and device vascularization.

Statement of Substantial Equivalence

The CODMAN Dural Graft Implant is substantially equivalent to DuraGen Dural Graft Matrix (K982180), Codman Bicol Collagen Sponge (pre-amendment), and Codman Ehtisorb™ Dura Patch (K991413) based on the subject device's similarity to the predicate devices in intended use, material, design, physical and functional characteristics. Physical comparisons, bench testing, an animal study and a clinical literature review demonstrate that the CODMAN Dural Graft Implant is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2004

Ms. Elizabeth Dolan
Senior Regulatory Affairs Specialist
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K033395
Trade/Device Name: CODMAN Dural Graft Implant
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura substitute
Regulatory Class: II
Product Code: GXQ
Dated: January 9, 2004
Received: January 12, 2004

Dear Ms. Dolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033395

Device Name: CODMAN Dural Graft Implant

Indications For Use: The Codman Dural Graft Implant is intended for use in procedures where the repair or substitution of the patient's dura mater is needed.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milham

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K033395